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## REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. Claim 1 has been amended. The limitation in claim 1 concerning the steps involved in measuring an amount of hydrogen peroxide by the redox reaction is supported for example by claim 4 and page 7, lines 14-23. The limitation in claim 1 concerning the step of degrading the analyte with a protease to give a degradation product of the analyte either before or after causing the fructosyl amino acid oxidase to act on the glycated amino acid is supported for example by previous claim 3 and page 5, lines 7-12. Claim 1 also has been editorially amended to clarify that the glycated protein is the analyte and is supported for example by page 5, line 32. Claim 1 further has been editorially amended to clarify that the analyte remains in the sample and the glycated amino acid is removed from the sample when causing a fructosyl amino acid oxidase to act on the glycated amino acid present in the sample, and is supported for example by page 2, lines 20-24. Claim 3 has been canceled without prejudice or disclaimer. Claim 4 has been amended editorially. Claims 1-2 and 4-30 are pending. No new matter has been added.

### *Claim rejections - 35 U.S.C. § 112*

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to claim the subject matter of the present invention. Claim 1 has been amended, taking the issues noted in the rejection into account. Applicants submit that claim 1 is definite.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

### *Claim rejections - 35 U.S.C. § 103*

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP1 002874 A2 (Komori et al.) in view of Biochemistry, 1988, Vol. 27, pp. 5470-5476 (Montellano et al.) and further in view of US Patent No. 6,127,138 (Ishimaru et al.). Applicants respectfully traverse this rejection.

Komori teaches a method of measuring an analyte in a sample using a redox reaction. The reference teaches that the analyte may be components in erythrocytes, including glycated protein. The reference further teaches that hydrogen peroxide is formed by decomposing sugar portions of glycated proteins by oxidation with FAOD, and that glycated amino acids also are subjected to the action of FAOD. However, nothing in the reference teaches or suggests the method of measuring the amount of glycated protein as the analyte involving the

steps of causing a FAOD to act on a glycated amino acid present in the sample, so that the analyte remains in the sample and the glycated amino acid is removed from the sample, and then measuring the amount of the analyte as required by claim 1. Komori in fact notes that the components in the sample to be measured may also include glycated amino acid, thereby teaching away from claim 1. Therefore, claim 1 and the dependent claims are patentable over Komori for at least these reasons.

The rejection contends that the Applicant's argument is not found persuasive since Komori teaches treating glycated protein and glycated amino acids with fructosyl amino acid oxidase. However, the FAOD treatment step of Komori does not correspond to the step of causing a FAOD to act on a glycated amino acid present in the sample, so that the analyte remains in the sample and the glycated amino acid is removed from the sample as required by claim 1. In particular, paragraph [0056] of Komori makes it clear that the reference's FAOD treatment step involves the formation of hydrogen peroxide. Paragraph [0061] of Komori even states that because the hydrogen peroxide is formed after the FAOD treatment, it is preferable that the pretreatment step is performed before the FAOD treatment. As such, it is abundantly clear that the FAOD treatment of glycated protein and glycated amino acid in Komori involves the generation of hydrogen peroxide from the glycated protein and the glycated amino acids, and does not involve the specific degradation of glycated amino acids as required by claim 1. Nothing in Komori teaches or suggests a method of using FAOD as required by claim 1. Accordingly, claim 1 and dependent claims therefrom are further removed from Komori for these reasons.

The rejection further contends that since several FAOD enzymes with varying substrate specificities were known in the art at the time the invention was made, it would have been obvious to choose enzymes which would fit for the purpose of a specific analysis. Applicants respectfully contend that the rejection's analysis of Komori clearly has been tainted by the improper use of hindsight. More specifically, the cited reference clearly fails to identify the problem of having glycated amino acids as exogenous substances in the sample and recognize the solution provided by claim 1. As such, merely varying the type of FAOD used in Komori would not lead to claim 1, as the FAOD treatment of Komori clearly does not involve removing unwanted glycated amino acid from the sample such that the glycated amino acid itself is not measured. Nothing in Komori teaches, suggests or provides any

motivation to remove glycated amino acid using an FAOD, so that the glycated protein, but not the glycated amino acid can be measured. Therefore, claim 1 and the dependent claims therefrom are even further removed from the reference for these reasons.

As to claim 6, the claim requires aging a solution containing the tetrazolium compound and the sodium azide by leaving the solution to stand at a temperature in the range from 20°C to 60°C for 6 to 120 hours and then adding the solution to the sample. Nothing in Komori, Montellano or Ishimaru teach or suggest a method of adding to the sample a solution that is aged as required by claim 6. Therefore, claim 6 is patentable over the references, taken alone or separately.

Claim 9 is directed to a measuring kit. Claim 9 requires the measuring kit to include a pretreatment reagent for preteating a sample containing a first FAOD, and a color-developing reagent containing a second fructosyl amino acid oxidase, an oxidoreductase and a color-developing substrate. The rejection contends that there would have been a reasonable expectation of success at the time the invention was made to combine the steps of the method of measuring an amount of glycated protein taught by Komori in an apparatus that was recited by Ishimaru. However, Komori does not teach a method involving a pretreatment step using a first FAOD. Therefore, even if Komori, Montello and Ishimaru are combined, the reference at best would teach a measuring kit having a color-developing reagent. Accordingly, claim 9 and the dependent claims therefrom are patentable over the references, taken alone or separately.

***Double Patenting***

Claims 1-30 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-22 of US Patent No. 6,790,665 (Yonehara). Applicants respectfully traverse the rejection.

Claims 1-22 of Yonehara recite a method where FAOD is used to generate hydrogen peroxide from a degraded glycated protein, which includes glycated amino acid derived from the glycated protein. However, the claims fail to recite the steps of causing a fructosyl amino acid oxidase to act on a glycated amino acid present in the sample, so that the analyte remains in the sample and the glycated amino acid is removed from the sample, and then measuring the amount of the analyte. Therefore, claim 1 and the dependent claims therefrom of the present application are patentable over Yonehara. Furthermore, Yonehara fails to recite or

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suggest a measuring kit having a pretreatment reagent containing a first FAOD for the pretreatment of the sample, and a color-developing reagent containing a second FAOD for the color-developing reaction. Therefore, claim 9 and the dependent claims therefrom of the present application are patentable over Yonehara.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.



Respectfully submitted,

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. Box 2902
Minneapolis, MN 55402-0902
(612) 455.3800

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By: _____
Douglas P. Mueller
Reg. No. 30,300